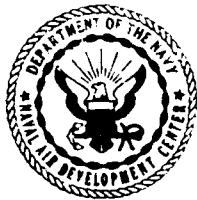


Report No. NADC-91035-60



AD-A238 748



NAVAL AIR DEVELOPMENT CENTER MEDICAL STANDARDS FOR RESEARCH SUBJECTS EXPOSED TO HAZARDOUS AEROSPACE ENVIRONMENTS

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FOREWORD

These medical research standards endeavor to ensure MAXIMUM SAFETY for volunteer subjects participating in aerospace medical research and development studies performed to support the naval air warrior. As with any standard, they are provided as GUIDELINES to be administered with careful judgment to serve the needs of the Naval Air Development Center and the U.S. Navy. Medical judgment requires a fine balance between minimizing experimental subject risk and meeting the operational needs of naval aviation. Naval combat aircrew risk their lives daily. Excess or undue hesitation in accomplishing research that could significantly enhance aircrew safety and combat performance, in the long run, may be of at least equal importance to experimental subject safety. A balance between optimum safety and the most rapid accomplishment of aerospace research is frequently required. It is very likely that any medical misadventure in aerospace research involving human research subjects would be equally detrimental for the research subject, aerospace research, and naval aircrew. Prolonged cessation of operationally important research must always be considered a potential result of a medical misadventure. It is for this reason that assurance of experimental subject safety is a team effort of all concerned with aeromedical research. The research team relies heavily on the professional expertise of the medical officers who are

integral members of the research team. The medical standards that have been developed in this document have included all of these considerations.

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INTRODUCTION

The aerospace environment of combat aircrew is a complex combination of stresses that threaten aircrew performance and survival. Aerospace medical and physiologic research endeavors to enhance aircrew performance and safety in that diverse aerospace stress environment. Much of this research requires human subject exposure to understand human factors and physiologic response to the aviation stress environment. In addition, developmental testing and evaluation of protective equipment and techniques ultimately require human evaluation prior to final operational testing and implementation. Maximum care must be exercised when exposing human volunteer subjects to the stress environments which are frequently at the very frontier of exceeding human physiologic and anatomic structural tolerance. To ensure human safety, medical standards must be established for minimizing the risk for inadvertent injury or even death during exposure to these severely stressful environments. Much of the research involves stress levels that exceed those present in the current operational environment.

In support of U.S. Navy and Marine combat aircrew, research at the Naval Air Development Center is performed in several environmental stress areas including sustained acceleration, ejection, thermal extremes, and radiation (laser) threats to the visual system. Medical standards which are specifically designed to maximally ensure volunteer subject safety during participation

in each of these research areas have been developed. The purpose of this report is to describe the medical standards for each of the major research areas requiring human subjects at the Naval Air Development Center. The medical standards are conservative and by design "err" on the side of safety. Excessive conservatism must, on the other hand, be balanced by an awareness of the continual and ever-increasing scarcity of qualified human volunteers available as experimental analogs of combat aircrewmembers. Consideration of the best interests of the U.S. Navy must also be balanced in establishing these medical standards. Public criticism of naval aerospace research, should any misadventure occur, remains a constant concern in the modern American society oriented toward individual rights and safety. There is little doubt that any mishap in research involving human subjects would result in a paralysis of research efforts for an extended period. Any slowing of research and development program progress ultimately affects operational readiness and the combat aircrewmembers for whom our entire efforts are devoted.

A hierarchy of medical requirements has been developed for each of the stress environments. This requirements structure is not solely based on safety, but by necessity, on the availability of clinical medicine support and cost containment. The Naval Air Development Center is unique as a research facility. There is very little co-located Naval Medical subspecialty support available and no on-site hospital. For these reasons, medical qualifications require maximum rigor to ensure prevention of any

medical misadventure. Without co-located medical support to provide rapid accomplishment of portions of the required tests and evaluations, it is probable that long lead times will be required to achieve subject qualification. It will be the responsibility of all medical personnel at the Naval Air Development Center to streamline the subject qualification process to meet the needs of aerospace research and development studies. The entire process of recruiting, qualifying, retaining, and ensuring the welfare of all volunteer research subjects for the duration of their participation requires a spirit of teamwork from all members of the Naval Air Development Center.

Centrifuge/Dynamic Flight Simulator Description

I. Manufactured by: McKiernan Terry Corporation

II. Installed: 1949

III. Design:

A. Arm:

1. Arm length: 50 foot
2. Maximum G: 40
3. Onset Rate: 13 G/sec Instantaneous
10 G/sec average from 2G to 10G
4. Motor Drive: 16,000 Effective hp, Direct DC

B. Gimbal System:

1. Dual Axis
2. Unlimited motion

C. Gondola:

1. Shape: Spherical, 10 foot diameter
2. Payload: 1000 pounds to 40 G
2000 pounds to 20 G
3. Sliprings: 16 Power
19 Coaxial
89 Instrumentation
4. Rotary Joints: Air Conditioning/Vacuum 15 psi
Hydraulic 3000 psi
Compressed Air 100 psi

D. Other Capabilities:

1. Computer Control
2. Cockpit Display Systems

E. Applications:

1. Sustained G Flight Simulation (Dynamic Flight Simulator)
 - a) F-14
 - b) F-18 (in development)
2. Combined Stress
 - a) Acceleration
 - b) Vibration
 - c) Altitude
 - d) thermal
 - e) Pilot Workload

IV. Research Mission: Investigation of the rapid-onset, sustained high G environment. Determination of the tolerance and psychophysiologic responses to this environment, alone and in combination with other environmental stresses. Development of equipment, techniques, and procedures which enhance the safety and performance of Navy and Marine combat aircrew.

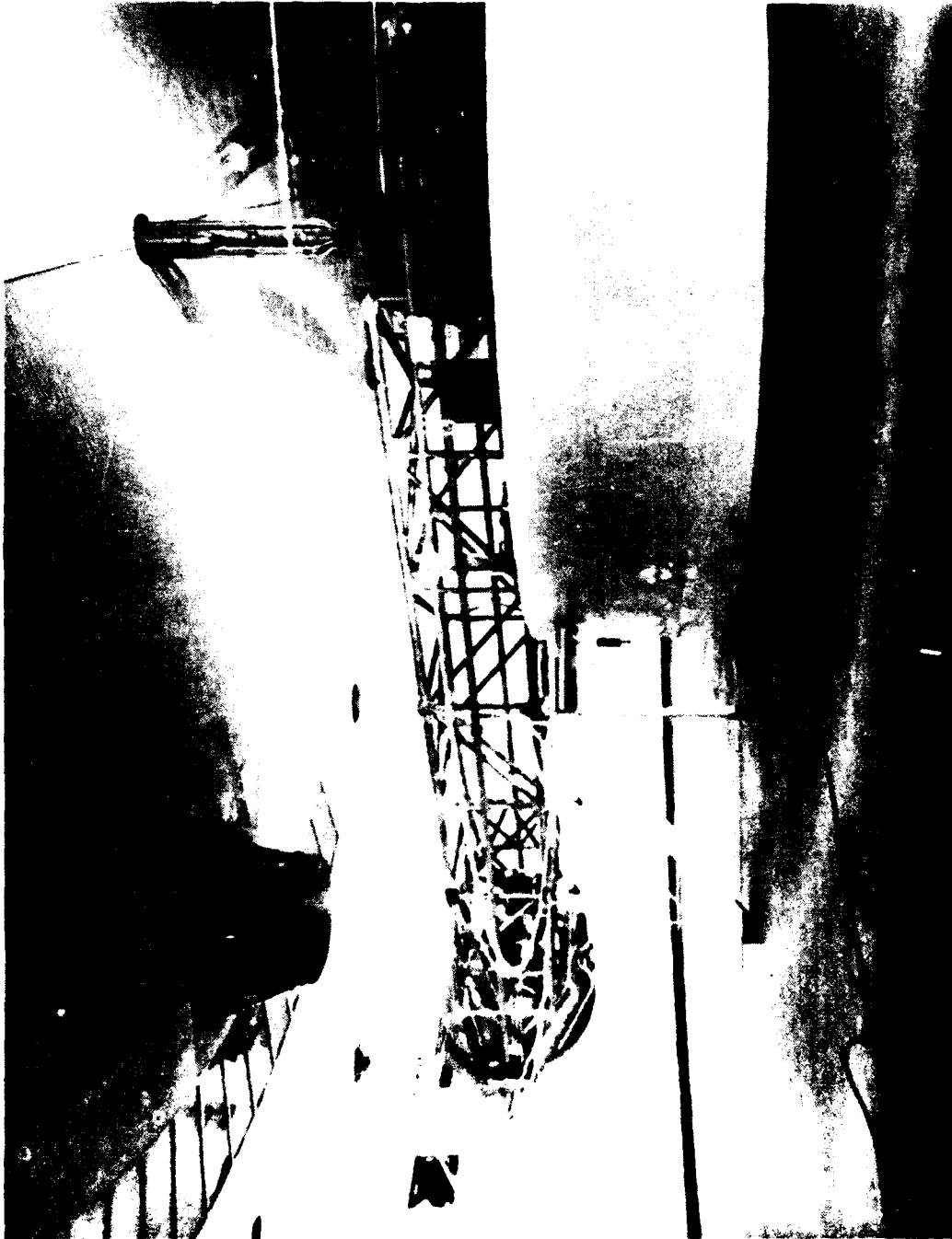


Figure 1. Naval Air Development Center Centrifuge/Dynamic Flight Simulator.

II. CENTRIFUGE ACCELERATION STRESS MEDICAL STANDARDS

The Naval Air Development Center human centrifuge, with its dynamic-flight-simulator (DFS) capability, is the finest acceleration research facility in the United States (and the free world). In addition to acceleration stress, it has the capability of combined hypobaric, vibration, and thermal stress. The acceleration characteristics of the 50 foot radius centrifuge are provided in the description of the facility. Since successively higher levels of G-stress, instantaneous G-onset rates, and longer duration of sustained G-stress increase the elements of human stress and risk of injury, an increasing degree of medical requirements, based on the magnitude of stress is required for qualification of experimental subjects. The design of this centrifuge provides a severe challenge for rapid medical rescue and egress of the subject from the elevated gondola which is not at ground level. Although somewhat arbitrary, and based on experience in the safe conduct of acceleration research, the standards for acceleration stress envelopes have become increasingly more stringent. Table I and II describe the stepwise procedure for medical qualification to levels of stress up to and including $+10G_z$ and levels of stress above $+10G_z$, respectively. The qualification steps will generally be accomplished in succession, since they represent increasing cost (time and money) and a small but finite increase in prospective subject risk to the medical tests. These standards are similar

to those previously established at other centrifuge acceleration research government laboratories (4).

Step 1. Normally a U.S. Navy Flying Class II Physical Examination will be the initial requirement. Other physical examinations may be acceptable, including U.S. Air Force Flying Class II or III and Federal Aviation Administration Class I and II physical examinations. A copy of the physical examination must be in the experimental volunteer subject's exposure file at the Naval Air Development Center prior to centrifuge exposure. Successful completion of the physical examination (aviation qualified) is not necessarily required. Certain medical standards may be disqualifying for flying but not disqualifying for centrifuge hazardous duty. Final authority for acceleration hazardous duty medical qualification resides with the Chief Aeromedical Scientist and Chief, Medical Operations; Naval Air Development Center.

Blood cholesterol and lipid profiles will be required, with calculation of cardiovascular risk. Excessive cardiovascular risk may be reason for disqualification. The risk calculation for qualification as an experimental subject is based on the USAF School of Aerospace Medicine (USAFSAM) risk index defined by the following formula:

$$RI = Age^2 \frac{TCHOL - HDL CHOL}{HDL CHOL}$$

where RI is the risk index, TCHOL is the total cholesterol, and HDL CHOL is high density lipoprotein cholesterol (1). This risk index, a dimensionless number which expresses the risk of angiographic coronary artery disease, was developed from a population of apparently healthy aviators undergoing aeromedical evaluation. This asymptomatic aircrew population is an appropriate group for which Naval Air Development Center volunteer subjects should be representative. A risk index of 12,000 or greater would be considered as potentially disqualifying. An abnormal treadmill exercise test will be disqualifying, irrespective of the risk index calculation. This is not based on the predictive accuracy for detection of coronary artery disease from the treadmill exercise response, in the population under consideration, but on the unknown, potential risk to the subject in a high stress environment as described in Step 3.

Pulmonary function testing will be included in this step. This is particularly important for acceleration research involving the use of positive pressure breathing.

Aeronautical adaptability must also be determined in this step. Based on the current standard set by the Naval Aerospace Medical Institute Psychiatry Department for Naval Aviation, it would be defined for human test subject qualification as follows:

Having the potential to adapt to the stress of the aerospace research environment by possessing the temperament, flexibility, and appropriate defense mechanisms necessary to suppress anxiety, maintain a compatible mood, and devote full attention to safety and the successful completion of a research project.

Personnel with DSM-III-R (Diagnostic Statistical Manual) Axis II diagnosis (Personality Disorder) are considered not aeronautically adaptable (NAA) and will be potentially disqualified. Furthermore, the research environment requires the test subject to possess a level of self-awareness sufficient to accurately and reproducibly report physical effects and medical conditions to medical monitors and research scientists. The inability to do so will result in disqualification from duties as a test subject. The final authority for aeronautical adaptability will reside with the Chief Aeromedical Scientist or the Chief, Medical Operations; Naval Air Development Center.

Step 2, +3G_z centrifuge orientation exposures will be used as a general screen to ensure minimum tolerance to the environment of the centrifuge. Since claustrophobia and severe motion sickness with nausea, vomiting, and disorientation are sometimes experienced by intolerant individuals, this orientation/familiarization serves to ensure minimal tolerance to this environment prior to progressing to more costly and time-consuming medical qualification procedures. Prospective subjects who are tolerant of the +3G_z centrifuge exposures and desire to continue toward qualification will be allowed to do so. (*Note:

Certain individuals desiring orientation to the centrifuge environment may be cleared for single exposure to centrifuge exposure to levels of $+3G_z$ after local clearance by the Chief Aeromedical Scientist or the Chief, Medical Operations, Naval Air Development Center without additional medical evaluation under certain unique circumstances.

Step 3 (along with the cholesterol/lipid measurements) is the major cardiovascular screening procedure. The exercise tolerance test is not utilized in the traditional clinical medicine manner. Coronary artery disease is unlikely in the population being considered as potential subjects, however it still remains a possibility (3). An abnormal ST-segment or T-wave response will be considered potentially disqualifying in spite of the low probability of diagnostic accuracy for coronary artery disease in young, asymptomatic individuals. The exercise test will be mainly used to ensure adequate physical fitness and to ensure that the prospective subject (1) has a normal blood pressure response, (2) achieves the predicted maximum heart rate response for their age ($220 - \text{age}$), and (3) has no predisposition to significant stress-induced cardiac rate/rhythm disturbances.

Since one of the major causes of sudden death in young adults is related to cardiac abnormalities which can be detected using echocardiographic techniques, the echocardiogram is a vital part of the medical qualification standards. The results of sudden death investigation in young athletes during, or just

after, exertional stress has revealed that structural cardiovascular disease was the most common etiology (2). At necropsy, the only organ system with significant anatomic abnormality was the heart. Hypertrophic cardiomyopathy was the most common cardiac abnormality in the athletes with sudden death. Overall, the most frequent causes of sudden death in the young athletes (hypertrophic cardiomyopathy, valvular disease, and aortic root dilation) could have been identified with echocardiography. These abnormalities will be disqualifying. Mitral valve prolapse, as determined by auscultatory or echocardiographic means, will be considered disqualifying even in asymptomatic, prospective subjects. Although conservative, the exact risk definition remains unclear for a certain subgroup of individuals with mitral valve prolapse, who may be predisposed to sudden death or life-threatening cardiac dysrhythmias (ventricular tachycardia and/or asystole). Based on altered autonomic balance resulting in cardiac rate and rhythm disturbances, these individuals may be at risk during acceleration stress, therefore, mitral valve prolapse will normally be considered disqualifying.

Step 4. Postero-anterior and lateral chest radiographs and a complete anteroposterior and lateral spine (cervical, thoracic, and lumbar) radiographic series, are included to assure normal cardio-pulmonary anatomy and adequate structural stability of the vertebral column, which is under considerable stress during rapid-onset, high-sustained centrifuge stress. The risk of

cervical neck injury is further increased by any added weight to the head and neck (flight helmet and accessories) and from whiplash-type strain in the event of the occurrence of $+G_z$ - induced loss of consciousness at high $+G_z$ -levels. Spinal abnormalities, in addition to those usually disqualifying for flight, will include: degenerative disc disease, Schmorl's nodes, certain congenital or acquired vertebral abnormalities, transitional vertebrae, and spina bifida occulta greater than one millimeter. In general, the recommendations of Kazarian will be followed for subject qualification (5). Radiology or other subspecialty consultation will be sought for questionable cases. Individual abnormalities will be reviewed on a case by case basis by the Chief Aeromedical Scientist and the Chief, Medical Operations; Naval Air Development Center.

Step 5. This includes medical screening for the presence of human immunodeficiency virus and hepatitis B, which should be considered a risk to research and biomedical support personnel, since blood studies and the risk of injury are a part of routine acceleration experimentation. Results of these tests will be considered extremely confidential.

The age limit of 40 is considered important since the risk of cardiovascular disease begins to significantly increase above age 35 and is further increased above age 40. Although conservative, as long as a sufficient number of subjects below age 40 are available, overall experimental safety should be

enhanced with this age restriction. Spinal mobility and strength begin to be significantly reduced above age 40, with overall experimental safety again being decreased. Unique individuals with a specific "need-to-know" or proven history of normal responses to stress will be considered on an individual basis for waiver by the Naval Air Development Center medical monitors. Qualified aircrew who are eligible for flight duties in fighter type aircraft will be eligible for centrifuge exposure without age restriction. Only males will be considered eligible for centrifuge exposure to levels above +9G_z. Although a controversial position, it is based on Naval Medical Command guidance along with the following reasons:

1. Lack of a current need to investigate female tolerance to the rapid-onset, high-sustained +G_z combat environment.
2. Physiologic differences between males and females which complicate experimental design, especially in studies with a very limited number of total subjects.
3. General Lack of upper body and neck strength in females.
4. The inability to absolutely assure continuous non-pregnancy prior to all centrifuge exposures.
5. The increased susceptibility of a certain subgroup of females to osteoporosis which may result in early weakening of the spinal skeletal structure.

Until a specific requirement to evaluate female tolerance to the aerial combat environment exists, or U.S. Navy policy and guidance regarding the use of females is expanded, experimental exposure of females (and potentially an unborn fetus) will be restricted to $+9G_z$. Female aircrew of fighter-type aircraft are not included in this restriction, as long as their normal duties include fighter-type aircraft flight exposure in the high $+G_z$ environment. Use of oral contraceptives will be a specific reason for potential disqualification based on the potential risk of thromboembolic problems in individuals taking them. Acceleration stress will be considered to substantially increase the risk of such problems. Table VI outlines the special considerations for qualification of female volunteer research subjects.

Table II describes the medical standards for acceleration exposure above $+10G_z$. Exposure to $+G_z$ stress greater than $+10G_z$ will require documented completion of 3 weeks of neck strengthening exercises (3 times per week). The subject must continue with this neck strengthening program to remain qualified for exposure above $+10G_z$. As described in Step 6, demonstrated proficiency and tolerance to the spectrum of $+G_z$ -exposures at $+10G_z$ and below will be considered mandatory. Determination of fulfilling the Step 7 neck strengthening criteria will reside with the Chief Aeromedical Scientist/Chief, Medical Operations, and project scientists at the Naval Air Development Center. A record of this conditioning will be maintained.

Since sudden cardiac death is one of the major risks to experimental subjects in several areas of aerospace medical research and electrocardiographic monitoring is used in these research areas, it is necessary to describe electrocardiographic standards in more detail. Table VII describes the electrocardiographic abnormalities and irregularities which are disqualifying for subjects and which will be reason for termination of exposure to a specific stress environment.

Finally, these standards are not intended to limit newer, sophisticated technologies from being utilized in the screening process. The information garnered from these tools may provide useful, high quality information for medical screening of test subjects. However, the blanket application of new technology for qualification decisions is strongly discouraged unless a large pool of information exists that establishes normal ranges in the population typical of NADC human test subjects (young, healthy males). As an example, recent experience at NADC and the United States Air Force School of Aerospace Medicine (USAFSAM) has demonstrated that magnetic resonance imaging (MRI), while an excellent research tool, is no more useful in identifying potentially disqualifying conditions of the spinal column than the physical standards currently in use at NADC and discussed in this manuscript. In general, a preferable approach is to apply and study any new medical technology in a series of test subjects and projects prior to its acceptance as a qualification tool. Of course, it is the prerogative of the Chief Aeromedical

Scientist and Chief, Medical Operations to use any means necessary to aeromedically evaluate a potential subject.

The basic concern for the well-being of all individuals exposed to G stress on the Naval Air Development Center centrifuge is the same; a fundamental difference exists, however, between exposures for reasons of training, medical evaluation of aircrew, and orientation to the G environment, as compared to exposure as a volunteer research subject. Research subjects are usually exposed repetitively to fatigue-limited, rapid-onset, high sustained G for an extended period (months to years). For the above reasons, these medical standards apply exclusively to volunteer research subjects. Aircrew undergoing operational exposure to the centrifuge environment for reasons of G-training will simply be required to possess a valid clearance for flying military fighter-attach aircraft. On the other hand, aircrew participating in projects other than training will be required to meet all medical processes for research subject qualification.

EJECTION SEAT TOWER DESCRIPTION

The NAVAIRDEVCON ejection seat tower is a 150 foot structure, inclined and supported at an angle of 20 degrees, 50 minutes from the vertical. It is the only tower of its kind in the free world. Initially built and utilized for ejection seat development by Martin-Baker in Great Britain, it was reconstructed at the Naval Air Development Center (then the Aeronautical Medical Equipment Laboratory) in 1946. The ejection tower is capable of +G_z acceleration from 6G to 30G with a total ejected weight from 120 pounds to 700 pounds. Ejection seats are propelled by pyrotechnics to simulate actual aircraft ejection in the boost phase. It is capable of accepting any current ejection seat and has been used for a variety of studies related to egress systems. Being man-rated, it is an important tool in determining the physiological acceptability of escape system acceleration forces using human volunteer subjects.

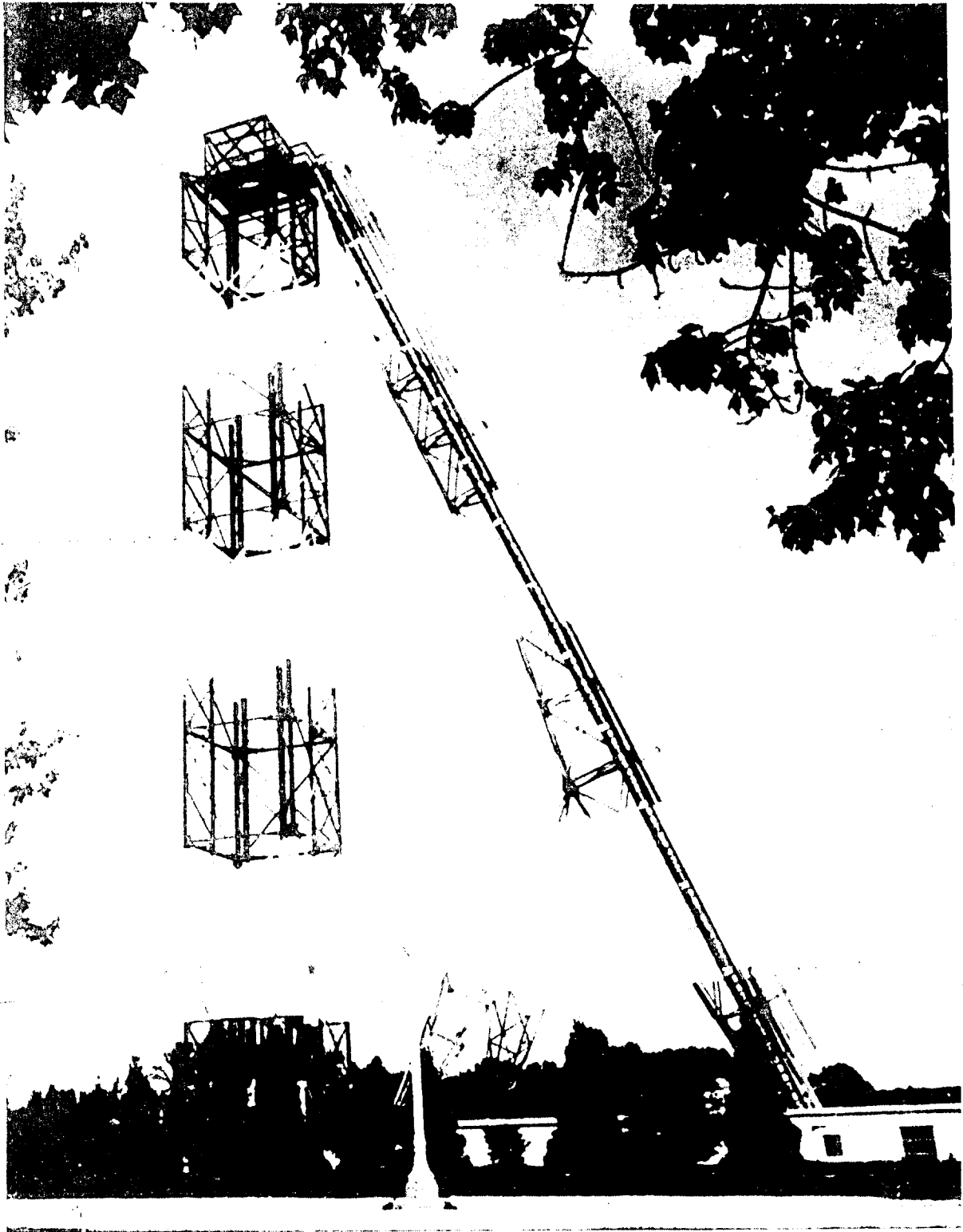


Figure 2. Naval Air Development Center Ejection Tower.

III. EJECTION STRESS MEDICAL STANDARDS

The emphasis of the medical screening for ejection stress qualification will be to assure that the risk of back and neck injury will be minimized. The 4 steps for qualification for ejection stress exposure will be as previously described for acceleration exposure. An exercise tolerance test is not required for ejection exposure, since cardiovascular stress assessed by this procedure are not a major part of ejection stress. Participation in a neck strengthening program as previously described is highly desirable. The age limit of 35 is even more conservative, but considered to enhance experimental safety. Waiver authority for age again resides with the Chief Aeromedical Scientist and Chief, Medical Operations as previously described. Since no one, including aircrew of fighter-type aircraft, are routinely exposed to ejection stress, all subjects must successfully complete these medical standard requirements. Participation in ejection stress studies will be limited to males, until additional guidance is provided by Naval Medical Command. The same considerations concerning MRI evaluation of the spine as described under Part II Centrifuge Acceleration Stress Medical Standards apply to ejection stress medical standards.

Environmental Research Laboratory Description

The environmental physiology laboratory evaluates aircrew clothing assemblies and related equipment in environmental conditions anticipated during flight and emergency scenarios, along with developing standards for the physiological limits which such systems must meet. Environmentally stressful scenarios dealt with in the laboratory include heat, dry cold, and cold water immersion.

Cold water immersion study can be performed with water temperatures controlled within the range of $+3^{\circ}$ to $+15^{\circ}\text{C}$. Waves, spray, and winds can be generated simultaneously to create a sea-like environment. Air temperatures can be independently maintained within the range of -40° to $+66^{\circ}\text{C}$. Heat stress studies examine the impact of ambient temperatures with controlled humidities.

The following are some of the applications for the laboratory: protective clothing evaluations, raft testing in a cold environment, physiological assessments of performance in a thermally stressful environment, rewarming procedures, and emergency procedures training in a realistic environment. The major thrust of the laboratory is to enhance the survivability of aviators in a hostile aquatic environment.



Figure 3. Naval Air Development Center Environmental Physiology Laboratory.

IV. EXTREMES OF THERMAL STRESS MEDICAL STANDARDS

The medical standards as described in Table IV are similar to those previously described. Spinal radiographic examination is not required. The age limit is increased to age 50 for individuals who will be allowed to participate as experimental subjects. The emphasis for qualification of subjects to participate in thermal stress studies will be to assure the absence of any reason that might result in an abnormal response to the thermal extreme of exposure. It is of critical importance to extend the tolerance envelope of individuals who may be exposed to environments involving thermal extremes.

Vision Laboratory Description

The Vision Laboratory is a comprehensive vision research facility which is equipped to support the conduct of a wide range of vision research and visual device evaluation. The apparatus of the laboratory consists of optical systems, contrast sensitivity measurement systems, perimeters, eye movement monitors, oculometers, spectrophotometers, photometers, radiometers, vertometers, a haze meter, visometer, filters, various light sources - including lasers, special purpose measuring devices and computers. The laboratory accommodates the conduct of research using human volunteers to assess the capabilities and limitations of the human visual system in environments created by advanced weapon systems and operational conditions.



Figure 4. Naval Air Development Center Vision Research Laboratory.

V. VISION (LASER THREAT PROTECTION) RESEARCH MEDICAL STANDARDS

As shown in Table V, participation in this type of vision research requires completion of an American National Standards Institute (ANSI) vision examination prior to, and upon completion of, participation in any study involving the use of LASERS or other similar radiation threats. The emphasis of the medical standards will be to assure that no harm occurs to the volunteer subjects during the course of participation in the vision studies.

VI. CONCLUDING REMARKS

The steps for qualification for acceleration, ejection, and extremes of thermal stress will be accomplished only once for initial qualification. Continuous qualification requires a valid physical examination (may not exceed 12 months from physical examination completion to an experimental exposure). The qualification for participation in vision research must be completed on a study by study basis.

These medical standards for human experimentation are not meant to be excessively restrictive. They are provided as specific guidelines to assist scientists and engineers in completing the safest and most meaningful aerospace research in a timely manner. The most costly delay in research and development, that will ultimately affect the combat aircrewman,

would be the injury or death of an experimental volunteer subject. As aerospace stress envelopes stretch the tolerance limits of the human body, medical standards assume increasing importance. Military research involving humans will increasingly be scrutinized by naval commanders and the American public. The entire research team, as a unified force, must work closely together to safeguard the privilege of conducting the safest human research possible.

It is important to recognize that the Naval Air Development Center research conducted will be judged against the existing standards at other Department of Defense laboratories. Our medical standards must at least conform to the medical standards which are in place at those sister research establishments. It will be a constant requirement to maintain a vigil of these sister laboratories' medical standards for human subject experimental subject exposures. The current standards are in line with the medical qualification standards at other Department of Defense laboratories in the United States and allied aerospace medical research laboratories.

Table I. Medical Standards Outline for Acceleration Stress
(+10Gz and Below)

- *Step 1. Completion of a U.S. Naval Flying Class II Physical Examination (or its equivalent) including blood cholesterol and lipid profile. This will include a standard pulmonary function test.
- Step 2. Familiarization to the Centrifuge Acceleration Environment (Maximum +G_z level of +3 G_z).
- Step 3. a. Exercise tolerance test. Maximal, fatigue limited test.
b. Two-dimensional echocardiogram.
- Step 4. Complete spinal radiographic evaluation (cervical, thoracic, and lumbar) and routine chest radiographs.
- Step 5. Special laboratory tests.
 - a. Human Immunodeficiency Virus (HIV) screening.
 - b. Hepatitis B screen.

*Age 11 it is 40 years with age waiver issued based on critical need to know. Qualification as fighter-type aircraft aircrew will not have age unit restriction.

Table II. Medical Standards Outline for Acceleration Stress
(Above +10Gz)

Steps 1 through 5 must be completed.

- Step 6. Demonstrated proficiency and tolerance to +10G_z and below.
- Step 7. Continuous participation in a neck strengthening program of at least 3 weeks duration prior to any exposure above +10G_z.
- Step 8. Magnetic Resonance Imaging (MRI) may be required for certain exposures. This may include imaging of the spine and/or central nervous system.

Table III. Ejection Stress Medical Standards Outline

- *Step 1. Completion of a U.S. Navy Flying Class II Physical Examination (or its equivalent) including blood cholesterol, lipid profile, and pulmonary function testing.
- Step 2. Two-dimensional echocardiogram.
- Step 3. Complete spinal radiographic evaluation (cervical, thoracic, and lumbar) and routine chest radiographs.
- Step 4. Special laboratory tests.
 - a. HIV screening.
 - b. Hepatitis B screen.
- Step 5. Magnetic Resonance Imaging (MRI) may be required before and after certain exposures. This may include imaging of the spine.

*Age limit is 35 years with age waiver based on critical need to know.

Table IV. Extremes of Thermal Stress Medical Standards
Outline

- *Step 1. Completion of a U.S. Navy Flying Class II Physical Examination (or its equivalent) including blood cholesterol, lipid profile and pulmonary function tests.
- Step 2.
 - a. Exercise tolerance test. Maximal, fatigue limited test using a modified protocol.
 - b. Two-dimensional echocardiogram.
- Step 3. Special laboratory tests.
 - a. HIV screening.
 - b. Hepatitis B screen.

*Age limit is 50 years with age waiver based on critical need to know or unique qualification (aircrew).

Table V. Vision (LASER Threat Protection) Research
Medical Standards

Step 1. American National Standards Institute (ANSI) vision examination. This examination will be required before and immediately after participation in each research study.

Table VI. Special Considerations for Qualification of Female Volunteer Research Subjects

1. No pregnant individuals will be allowed to participate in Naval Air Development research.
2. If a female subject becomes pregnant in the course of a research project she will be immediately restricted from further participation in the study. Female subjects will be required to sign a pre-participation agreement that stipulates they will notify medical/research personnel immediately upon confirmation or suspicion of pregnancy.
3. Each female subject will undergo pregnancy testing prior to participation in Naval Air Development Center research.
4. Contraceptive medication will be considered disqualifying.

The restrictions for female participation is not meant to be discriminatory in any way. They are meant to maximally ensure the safety of subjects and to prevent exposure of an unborn fetus to unnecessary and potentially hazardous environmental stress. Female aircrew, qualified for flight in fighter-type aircraft, will be qualified for experimental participation if they are qualified for such flight duties operationally. The maximum +G_z-level for female experimentation will be +9G_z on the centrifuge/dynamic flight simulator. Guidance provided by Naval Medical Command will be followed, with medical standards periodically altered to comply with their guidance.

Table VII. Electrocardiographic abnormalities and irregularities disqualifying or requiring termination of stress exposure for experimental subjects

I. Resting electrocardiogram

- a. Any electrocardiographic evidence of previous myocardial infarction or current myocardial ischemia. This includes marked T-wave abnormalities and ST-segment depression of 0.5 mm or greater.
- b. Evidence of marked ventricular hypertrophy ($Sv_2 + Rv_5 \geq 40$ mm) unless echocardiography reveals only evidence of isolated hypertrophy compatible with athletic training.
- c. Left or right bundle branch block.
- d. Wolff-Parkinson-White or other pre-excitation syndrome.
- e. Second or third-degree heart block. (Atrio-ventricular dissociation post-stress is not necessarily disqualifying.)
- f. QT-prolongation (QTc greater than upper limit of normal).
- g. Atrial dysrhythmias: atrial fibrillation or flutter, chaotic atrial mechanism, atrial tachycardia > 100 bpm, sinus tachycardia > 100 bpm.
- h. Ventricular dysrhythmias: ventricular fibrillation or flutter, ventricular tachycardia (3 or more consecutive ventricular ectopic beats with a rate > 90 bpm), multiformed premature ventricular contractions, paired premature ventricular contractions, frequent premature ventricular contractions (5 or more per minute on rhythm strip).
- i. Marked bradycardia (<50 bpm).

II. Electrocardiographic Response to Stress

The same abnormalities and irregularities as defined on the resting electrocardiogram will require stress termination and may be disqualifying if they are stress induced. In addition, the following will also require stress termination.

- a. Stress induced bradycardia or inappropriate reduction of heart rate during stress. Special consideration will be given to hypothermia studies where heart reductions may be physiologically normal.
- b. Sinus tachycardia stabilizing at a rate > 200 bpm or a peak heart rate of 210 bpm.
- c. Any dysrhythmia that results in sudden incapacitation in association with $+G_z$ -stress.

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